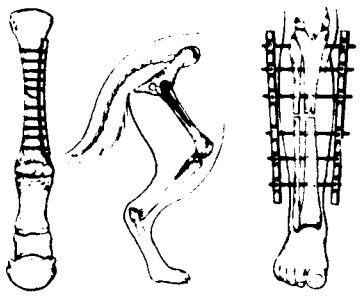


Comparative Orthopaedic
Research Laboratory

February 9, 1994

Defense Technical Information Center
Building 5, Cameron Station
Alexandria, VA 22304-6145

RE: Grant no. N00014-93-1-0745; The effect of cementation and autogenous bone grafting on allograft union and incorporation.

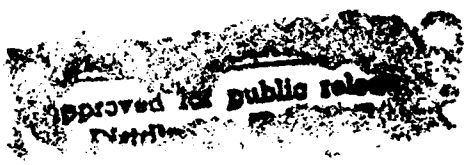
To whom it may concern:

Enclosed please find the progress report for the above referenced grant. We apologize for any inconvenience in the delay of your receiving this report. Our contract agreement indicates an annual report is required, although no due date is listed. We had assumed that date would fall on the anniversary of the grant (May 1, 1994) and did not realize the due date was January. In reality, funding was not received until July 12, 1993. Therefore, the enclosed progress report actually encompasses six months effort rather than a full year. We have requested to have the report due date clarified and will be happy to comply with that date in the future. Thank you for your assistance on this matter.

Sincerely,

Mark D. Markel

Mark D. Markel, DVM, PhD
Director, Comparative Orthopaedic
Research Laboratory



2015 Linden Drive West
Department of Surgical Sciences
School of Veterinary Medicine
University of Wisconsin–Madison
Madison, Wisconsin 53706
Laboratory Rooms 3321, 3325, 3238, 3226
(608) 263-9834, 1018, 9827
Fax: (608) 263-6573

Annual Performance Report

(Report Type (a))

Name and Address of the University:

Board of Regents of the University of Wisconsin System

Title of Project:

The Effect of Cementation and Autogenous Bone Grafting on Allograft Union and Incorporation

Grant Number:

N00014-93-1-0745

Principle Investigator:

Mark D. Markel, DVM, PhD

Covered Time Period:

May 1, 1993 to present (Period funded: July 12, 1993 to present)

Progress:

This study is designed to examine the reconstruction of bone after segmental bone loss. During the first six months of this project we have initiated Phase I of the study. The specific aims of this phase are to develop a normal data base for the structural stiffness (torsion, compression, and bending) and torsional strength of a mid-diaphyseal segmental replacement of the canine femur held in place by an interlocking nail with and without cementation of the medullary canal of the allograft. This information will serve as the base line for data for the initial fixation strength of these types of segmental defect repair.

For this phase of the study, 16 pairs of intact canine femora have been harvested, stripped of soft tissues, and stored at -70°C until ready for testing. A precision alignment jig made of plexiglass has been constructed to orient the bone specimen along its axis to ensure uniform load application. Fixation clamps have been designed to hold the bone in the correct alignment for compression, cantilever bending, and torsion tests.

Preliminary tests were performed with 3 intact bone specimens to evaluate the testing system using the conditions described in the original proposal. Briefly, all tests were performed on a commercially available materials testing machine (Bionix 858, MTS Systems, Minneapolis, MN). Bones were embedded in acrylic and positioned in the appropriate fixation clamp on the testing machine. Loads were applied through the clamp to the acrylic blocks, as will be done with experimental bones to avoid contact with the interlocking nail. Compression tests were performed at a loading rate of 450 N/min to a maximum load of 100 N. Cantilever bending was performed in a craniocaudal direction and then in a mediolateral direction at a loading rate of 450 N/min to a maximum load of 100 N. Torsion tests were performed with torque applied to the proximal portion of the femur in external rotation at 15°/min to a maximum of 45° or until failure. For all tests, load or torque and linear displacement or angular deformation were recorded. Load-deformation or torque-angular deformation curves were constructed and the slope of the linear portion of the curve was determined as an indicator of the rigidity or stiffness of the bone. For bending tests, the stiffness was multiplied by the moment arm to determine the bending resistance of the bone. Results of these preliminary tests were as follows:

Compressive stiffness:	395.8 N/mm
Craniocaudal bending stiffness:	234.3 N· m/rad
Mediolateral bending stiffness:	167.7 N· m/rad
Torsional stiffness:	96.2 N· m/rad
Maximal torque:	24.6 N· m.

The Phase I *in vitro* testing of intact control bones and experimental bones where the segmental allograft is held in place by an interlocking nail with or without the addition of medullary cement is currently underway utilizing a protocol similar to that described above. This testing should be completed by May 31, 1994.

In Phase II of this study, an *in vivo* dog model will be used to perform segmental replacement of the mid-diaphysis (6-cm) of the femur with an immunologically mismatched allograft stabilized with an interlocking nail with and without cementation of the medullary canal. Additionally, the effect of the addition of autogenous bone graft (periosteally, endosteally, or both periosteally and endosteally) on healing, mineral content, bone

remodeling, and limb function will be assessed. Surgeries for Phase II are scheduled to begin in June, 1994, and be completed by October, 1994. Dogs will be evaluated at regular intervals after surgery until they are euthanized at 6 months. Radiography will be performed at biweekly intervals to monitor periosteal callus formation. Dual energy X-ray absorptiometry will be performed monthly to assess changes in bone mineral content of the host bone and allograft. Static weight bearing will be evaluated biweekly through the use of digital bathroom scales. Dynamic weight bearing will be evaluated monthly with each dog walked over a force plate. The ground reaction forces will be determined from this data. From December, 1994, to April, 1995, dogs will be euthanized for final analysis. Mechanical testing will be performed as in Phase I, except that the interlocking nail will be removed prior to testing. Bone porosity will be quantitated through the use of backscatter electron microscopy. New bone formation will be quantitated by a tetracycline labeling technique performed throughout the experimental period. Data collection is expected to be completed by September, 1995. Statistical analysis, manuscript preparation, and presentation of findings will then follow. Completion of the project should occur on schedule.